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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,136	10/27/2000	Daniel Santi	300622004900	6454
7590 11/26/2003				
KOSAN BIOSCIENCES, INC. 3832 BAY CENTER PLACE HAYWARD, CA 94545			EXAMINER KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/699,136

Applicant(s)

SANTI ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 17, 24 and 26-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 17, 24 and 26-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection mailed February 21, 2003; Applicants filed a response and amendment on August 25, 2003. Said amendment amended Claims 1 and 24. Thus, Claims 1, 17, 24, and 26-39 are pending in the instant application and will be examined herein.

The Examiner notes that the presentation of pending claims is incorrect and/or incomplete in citing Claims 2-3, 14-16, 18-23, 25 (cancelled 5/14/02), and 40 (cancelled 11/26/02) as “withdrawn” since these claims are ---cancelled---. Moreover, the status of Claims 4-13 has been omitted (said claims have been cancelled on 5/14/02).

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/161,703 filed on October 27, 1999.

Drawings

3. The drawings have been approved by the Draftsman and are considered acceptable for publication upon allowance.

Compliance with the Sequence Rules

4. A new sequence listing, in computer readable form and paper copy, was filed on August 25, 2003; said listing has been entered. See new matter objection below.

Withdrawn - Objections to the Specification

5. Previous objection to the specification for inappropriate notation of an Internet address is withdrawn by virtue of Applicants' amendment.

6. Previous objection to the specification for having an incomplete reference is withdrawn by virtue of Applicants' amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 1, 17, 24, and 26-39 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment. Moreover, the Examiner notes that in the absence of SEQ ID NOs to describe genes in item (a) in Claim 1, the mutA and mutB genes has been reconsidered for issues of description. While a SEQ ID NO is required to describe the *P. shermanii* epimerase gene of item (b) (SEQ ID NO:5), the same is not required in item (a) because the gene names "mutA" and "mutB" define a genetic locus of the DNA of the organisms that is being claimed (a structure), not just a function (like that of encoding a methylmalonyl CoA mutase or epimerase). Clearly in view of the specification and the record, Applicants intend to limit the genes of item (a) to those specifically described in the art referenced in page 15 of the specification. Thus, in view of new matter issues presented below, the Examiner suggests rewriting Claim 1 to include (a) mmCoA mutase genes mutA and mutB from either *P. shermanii* or *S. cinnamonensis* and (b) a *P. shermanii* epimerase gene having the nucleotide sequence given in SEQ ID NO:5.

NEW ISSUES

Objections to the Specification

8. The amendment filed August 25, 2003 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NOs:1-4 in the sequence listing and their specific reference on page 15.

Applicant is required to cancel the new matter in the reply to this Office Action.

9. The specification is objected to for inappropriate notation of an Internet address. On page 48, lines 17-18, an Internet address is cited in an unacceptable form. See M.P.E.P. § 707.05(e) for the acceptable notation of an Internet address.

10. The specification is objected to for having inconsistent and/or unclear reference citations. In pages 1-52, all references are complete on the page cited. On page 53, line 21, and on page 70, line 16, references are cited only by Author and Year (unclear reference). Beginning on page 72 through page 92, references are cited with a number (beginning with “[3]”) and using a bibliography; no reference to citations 1-2 are found. Consistency and clarity in the citation of references is required throughout the specification.

11. The specification is objected to for being unclear. On page 55, lines 18 and 20, numbers found in parentheses that are unclear.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 17, 24, and 26-39 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specific sequences SEQ ID NOs:1-4, although referred to specifically in the specification on page 15 by way of non-patent literature citations, were not expressly incorporated by reference and were not a part of the specification as originally filed. Thus, their addition as new limitations in the claims is considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 17, and 26-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. By virtue of the claim language, it is unclear if the limitation of "said PKS gene being contained in a vector that replicates extrachromosomally or is integrated into the chromosomal DNA of such a host cell" is a real limitation on the host cell, i.e., the vector containing PKS gene(s) are required in the claimed host cell in addition to the required

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mutase and epimerase genes, or if it is merely used to describe the function of the products of the mutase and epimerase genes.

Clearly from the specification, the implied limitation is that the claimed host cell must also contain PKS genes, particularly since *E. coli* host cells do not naturally contain PKS genes. However, this limitation cannot be read into the claims, which literally only use the PKS genes as a descriptor of the mutase and epimerase genes. The Examiner suggests rewriting the claim language so that the claimed *E. coli* host cell contains a) mutA and mutB mutase genes from the specific organisms, b) epimerase gene that is SEQ ID NO:5, and c) modular PKS genes. With this change, the Examiner notes that Claim 1 would be identical in scope to Claim 24; Applicants may consider canceling one of these claims.

14. Claims 1, 17, and 26-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, the phrase “wherein the products of said methylmalonyl CoA mutase and said epimerase genes are effective” is unclear since nucleotide sequences have many “products” such as proteins, mRNA, etc. The Examiner suggests amending the language to be “wherein the proteins encoded by said mmCoA mutase and said epimerase genes...” for clarity.

15. Claim 34 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At the end of the claim “or a gene” is an orphan phrase with unclear meaning; its deletion is required.

Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:
- a) The amendment filed August 25, 2003 stands objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure in the sequence listing and the specification.
 - b) The specification stands objected to for inappropriate notation of an Internet address.
 - c) The specification stands objected to for having inconsistent and/or unclear reference citations.
 - d) The specification stands objected to for being unclear on page 55, lines 18 and 20.
 - e) Claims 1, 17, 24, and 26-39 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
 - f) Claims 1, 17, and 26-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the limitation of including PKS genes in the claimed host cell.
 - g) Claims 1, 17, and 26-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for "the products" of the genes.
 - h) Claim 34 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for an orphan phrase with unclear meaning.


Conclusion

17. Claims 1, 17, 24, and 26-39 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. The instant Office action in **NON-FINAL** in view of the new grounds of rejection presented herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK 
November 18, 2003